Message

From: Tanner, Barbara [Tanner.Barbara@epa.gov]
Sent: 5/30/2019 4:05:30 PM
To: Faeth, Lisa [Faeth.Lisa@epa.gov]; Anderson, Steve [Anderson.Steve@epa.gov]; Askinazi, Valerie [Askinazi.Valerie@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]; Barkas, Jessica [barkas.jessica@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Blair, Susanna [Blair.Susanna@epa.gov]; Buster, Pamela [Buster.Pamela@epa.gov]; Canavan, Sheila [Canavan.Sheila@epa.gov]; Caraballo, Mario [Caraballo.Mario@epa.gov]; Carroll, Megan [Carroll.Megan@epa.gov]; Cherepy, Andrea [Cherepy.Andrea@epa.gov]; Christian, Myrta [Christian.Myrta@epa.gov]; Corado, Ana [Corado.Ana@epa.gov]; Davies, Clive [Davies.Clive@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Devito, Steve [Devito.Steve@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Drewes, Scott [Drewes.Scott@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Edmonds, Marc [Edmonds.Marc@epa.gov]; Elwood, Holly [Elwood.Holly@epa.gov]; Fan, Shirley [Fan.Shirley@epa.gov]; Farquharson, Chenise [Farquharson.Chenise@epa.gov]; Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; Feustel, Ingrid [feustel.ingrid@epa.gov]; Frank, Donald [Frank.Donald@epa.gov]; Gibson, Hugh [Gibson.Hugh@epa.gov]; Gimlin, Peter [Gimlin.Peter@epa.gov]; Gorder, Chris [Gorder.Chris@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Grant, Brian [Grant.Brian@epa.gov]; Gray, Shawna [Gray.Shawna@epa.gov]; Groeneveld, Thomas [Groeneveld.Thomas@epa.gov]; Guthrie, Christina [Guthrie.Christina@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Helfgott, Daniel [Helfgott.Daniel@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kapust, Edna [Kapust.Edna@epa.gov]; Kemme, Sara [kemme.sara@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]; Krasnic, Toni [krasnic.toni@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Lee, Mari [Lee.Mari@epa.gov]; Lee, Virginia [Lee.Virginia@epa.gov]; Leopard, Matthew (OEI) [Leopard.Matthew@epa.gov]; Liva, Aakruti [Liva.Aakruti@epa.gov]; Lobar, Bryan [Lobar.Bryan@epa.gov]; Menasche, Claudia [Menasche.Claudia@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Moyer, Adam [moyer.adam@epa.gov]; Myers, Irina [Myers.Irina@epa.gov]; Myrick, Pamela [Myrick.Pamela@epa.gov]; Nazef, Laura [Nazef.Laura@epa.gov]; Ortiz, Julia [Ortiz.Julia@epa.gov]; Owen, Elise [Owen.Elise@epa.gov]; Parsons, Doug [Parsons.Douglas@epa.gov]; Passe, Loraine [Passe.Loraine@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Pratt, Johnk [Pratt.Johnk@epa.gov]; Price, Michelle [Price.Michelle@epa.gov]; Reese, Recie [Reese.Recie@epa.gov]; Reisman, Larry [Reisman.Larry@epa.gov]; Rice, Cody [Rice.Cody@epa.gov]; Richardson, Vickie [Richardson.Vickie@epa.gov]; Ross, Philip [Ross.Philip@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]; Santacroce, Jeffrey [Santacroce.Jeffrey@epa.gov]; Saxton, Dion [Saxton.Dion@epa.gov]; Scarano, Louis [Scarano.Louis@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Scott Selken [spselken@up.com]; Scott, Elizabeth [Scott.Elizabeth@epa.gov]; Selby-Mohamadu, Yvette [Selby-Mohamadu.Yvette@epa.gov]; Seltzer, Mark [Seltzer.Mark@epa.gov]; Sheehan, Eileen [Sheehan.Eileen@epa.gov]; Sherlock, Scott [Sherlock.Scott@epa.gov]; Simons, Andrew [Simons.Andrew@epa.gov]; Sirmons, Chandler [Sirmons.Chandler@epa.gov]; Slotnick, Sue [Slotnick.Sue@epa.gov]; Smith, David G. [Smith.DavidG@epa.gov]; Smith-Seam, Rhoda [smith-seam.rhoda@epa.gov]; Stedeford, Todd [Stedeford.Todd@epa.gov]; Stevens, Katherine [stevens.katherine@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]; Symmes, Brian [Symmes.Brian@epa.gov]; Thompson, Tony [Thompson.Tony@epa.gov]; Tierney, Meghan [Tierney.Meghan@epa.gov]; Tillman, Thomas [Tillman.Thomas@epa.gov]; Tomassoni, Guy [Tomassoni.Guy@epa.gov]; Tran, Chi [Tran.Chi@epa.gov]; Turk, David [Turk.David@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Wallace, Ryan [Wallace.Ryan@epa.gov]; Wheeler, Cindy [Wheeler.Cindy@epa.gov]; Widawsky, David [Widawsky.David@epa.gov]; Williams, Aresia [Williams.Aresia@epa.gov]; Williams, Bridget [Williams.Bridget@epa.gov]; Williamson, Tracy [Williamson.Tracy@epa.gov]; Wills, Jennifer [Wills.Jennifer@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]; Wolf, Joel [Wolf.Joel@epa.gov]; Wright, Tracy [Wright.Tracy@epa.gov]; Yowell, John [yowell.john@epa.gov]; Tanner, Barbara [Tanner.Barbara@epa.gov]
Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

EPA Fills Southeast Post, Six Months after Prior Chief Indicted

By Chris Marr
Posted May 28, 2019, 2:39 PM

The EPA's southeast region officially has a new administrator—six months after its previous region chief resigned following his criminal indictment.

EPA Solvent Rule Bars Legitimate Business Sales, Lawsuit Argues

By Pat Rizzuto
Posted May 29, 2019, 2:38 PM

An EPA rule blocking consumer uses of some paint strippers would wrongly stop retailers from selling methylene chloride-based products to contractors and small businesses, solvent makers challenging the directive say.

Sweden Stakes Out Its Turf on Microplastics in Fake Grass

By Marcus Hoy
Posted May 30, 2019, 1:00 AM

New measures are needed to protect waterways and marine life by curbing the release of microplastics from fields and playgrounds made with artificial turf, Sweden's environment agency said.

New Hampshire Gov. Chris Sununu (R)
Photographer: Shannon Finney/Getty Images

News

New Hampshire Sues 3M, DuPont Over Nonstick Chemicals (1)

Posted May 29, 2019, 1:15 PM Updated May 29, 2019, 7:33 PM

- Nonstick chemicals have contaminated N.H. waterways, governor says
- State blames manufacturers in state court lawsuits

DuPont, 3M, and other chemical manufacturers should pay for their nonstick compounds' contamination of New Hampshire's waterways, the state said in two lawsuits filed May 29.

Four types of the companies' fluorinated chemicals have contaminated the state's groundwater, surface water, and fish, wildlife, and marine resources, and the companies should pay all costs for investigating and cleaning up the contaminants, according to two lawsuits filed against the manufacturers in state Superior Court.

The lawsuits are the latest by states against manufacturers over contamination by per- and polyfluoroalkyl (PFAS) chemicals, which are used in nonstick coatings and firefighting foam. Delaware, Michigan, New Mexico, and New Jersey have also recently filed suits against manufacturers over alleged PFAS contamination.

The PFAS chemicals persist in the environment and have been found in drinking water systems nationwide. The federal Environmental Protection Agency has linked two types of PFAS chemicals to cancer and immune and liver problems.

The lawsuits "will provide proper assistance to the state and our communities," Gov. Chris Sununu (R) said in a news release.

In addition to 3M Co. and DuPont Co., the state is suing Buckeye Fire Equipment Co., The Chemours Co. LLC, Chemguard Inc., Kidde-Fenwal Inc., National Foam Inc. and Tyco Fire Products LP.

PFAS in Wells

In 2016, PFAS chemicals were found in the private drinking water wells of more than 500 families in New Hampshire. The contamination was traced to a former ChemFab Corp. plant in Bennington, Vt., now owned by Saint-Gobain Performance Plastics.

New Hampshire then launched a broad investigation to locate PFAS contamination in drinking water, groundwater and elsewhere in the state, an effort that remains underway.

New Hampshire alleges that the companies are responsible for contaminating the state with four common PFAS: perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA) and perfluorohexanesulfonic acid (PFHxS).

The companies knew the chemicals were harmful but continued to make and sell them without warning the public of their health risks, New Hampshire Attorney General Gordon MacDonald (R) said.

"3M cares deeply about the safety and health of New Hampshire's communities," the company said May 29. "3M acted responsibly in connection with products containing PFAS and will vigorously defend its environmental stewardship."

In addition to the lawsuits, New Hampshire will submit strengthened proposed drinking-water standards to the state's rulemaking body "in the coming weeks," Sununu said.

Chemours did not immediately respond to Bloomberg Environment's request for comment.

The cases are New Hampshire v. 3M Co., N.H., docket number unavailable, 5/29/19 and New Hampshire v. 3M Co., N.H. Super. Ct., docket number unavailable, 5/29/19.

https://news.bloombergenvironment.com/environment-and-energy/new-hampshire-sues-3m-dupont-over-nonstick-chemicals-in-water

Cuba-U.S. scientific cooperation declines under Trump

Published: Wednesday, May 29, 2019

The degradation of relations between the U.S. and Cuba under President Trump has begun to cut into scientific cooperation on issues ranging from treatment of infectious diseases to coral reef preservation.

A biomedical fellowship exchange program has been put on hold. Cuban cardiac nurses have stopped providing training to universities in Georgia and Maryland. A Cuban marine researcher has stopped accepting invitations to events in the U.S. because it's nearly impossible to get visas.

The United States has enforced a trade embargo against Cuba since the early 1960s. However, President Obama started a more open relationship with the island in 2014, leading to soaring numbers of American trips for cultural and educational exchanges.

The Trump administration has reversed course.

Washington recently announced a new cap on the amount of money that families in the U.S. can send relatives in Cuba. The U.S. also has opened the way for lawsuits against foreign firms operating on properties that Cuba seized from Americans after the 1959 revolution, including suits by Cubans who later emigrated to the United States.

Patricia González, director of the University of Havana's Center for Marine Research, said she used to travel often to the U.S. for meetings and to visit laboratories, but now she declines the invitations she gets.

"The number of scientific visas that they [the U.S.] are giving is minimal. It is nothing compared to before, when it was really difficult to deny an academic visa," she said.

González also said some U.S. scientists are afraid of traveling to Cuba, worried about some sort of retaliation when they return to the U.S. Travel difficulties in both directions, she said, "have really hurt the academic relationship."

Taking care of species like sharks or endangered sawfish only makes sense if it is done regionally because they travel all around, González said. The same regional approach needs to be taken for climate change or natural disasters, she added.

"What happens if there is an oil spill in the Gulf of Mexico? How are we going to jointly face the problem? Because that is a threat that exists," she said.

Some scientists try to be optimistic.

"We have been able to ride the waves of political relations, and we hope to be able to continue to do that," said Dan Whittle, senior director with the New York-based Environmental Defense Fund, which has worked with Cuban universities, research centers and the Cuban government for 19 years on marine and coastal conservation.

"Science and the environment transcend politics," Whittle said. — *Claudia Torrens, Associated Press*

https://www.eenews.net/greenwire/2019/05/29/stories/1060424123

CHEMICAL WATCH ARTICLES

Washington state HFC, paint stewardship bills become law

30 May 2019 / Built environment, US states

Washington state governor Jay Inslee has signed into law legislation addressing hydrofluorocarbons (HFCs) and another on paint production and waste.

HB 1112 aims to reduce greenhouse gas emissions from HFCs by phasing out the substances' use in certain products, such as in polyurethane and refrigerating applications.

Meanwhile, HB 1652 imposes extended producer responsibility and product stewardship obligations on paint companies.

A 'stewardship organisation' representing producers will need to submit a plan to implement a stewardship programme by 28 July 2020.

The governor signed both measures into law on 9 May.

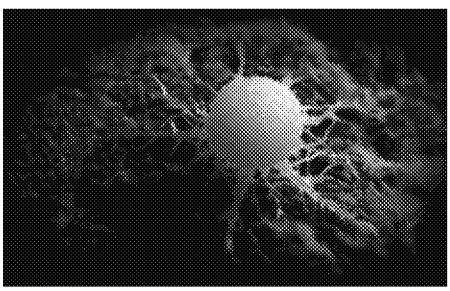
Related Articles

- Washington state paint stewardship, HFC bills head to governor
- **Further Information:**
- HB 1112
- HB 1652

US NTP to focus on human biology for risk assessment

Starting with cancer and including research into 'environmental factors'

30 May 2019 / Alternative approaches to testing, CMRs, United States



The US National Toxicology Program (NTP) is working to bring human biology and data into risk assessment and move away from animal testing, according to Warren Casey, director of the NTP's Interagency Center for the Evaluation of Alternative Toxicological Methods (Niceatm).

"We really need to get better at understanding the entire spectrum of human disease and be able to use mechanistic studies instead of animal studies" to identify when adverse effects might occur, he said.

The NTP is initially focusing on three health innovation programmes for cardiovascular toxicity, developmental neurotoxicity and carcinogenicity.

"The cancer testing is really where I think we will be able to make the biggest impact on the use of animals and work this paradigm where using human data will inform our testing", said Dr Casey at a public forum for the NTP's Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) on 23 May.

The NTP is free to try a new model because it is "not obligated to use any specific method", he said. "We don't have policy that tells us what to do. We don't have guidance or guidelines. We don't have that regulatory burden that a lot of agencies have because they have that historical requirement or guideline. So we are really in a place to work a new paradigm with our partners and to see if that works," he said.

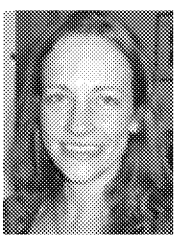
Rodent cancer

Dr Casey spoke of a need to move away from traditional tests to see whether a chemical may cause cancer in rodents. "Cancer is over 100 different diseases so we are trying to put chemicals into rodents at doses that have no human relevance and then predict one of 100 different diseases on the other side," he said. "That works for some things but we are really into the area now where we need to be more subtle and a little more nuanced on how we do the assessments."

The NTP will look at what environmental factors may be contributing to an increasing incidence or mortality for a certain kind of cancer in humans. This will include "using the data that are already out there to identify populations that are already affected, understanding the environmental causes and then using that knowledge to build our knowledge base so we can be more predictive about new chemicals," he said.

He pointed to regional differences in cancer incidence. "Are they driven by environmental factors?" he asked. "Maybe. This is the type of thing we need to start investigating."

He spoke of a need to find a middle ground where scientists can start using mechanistic information to make assessments instead of having to rely on the animal model. "The future is going to be human-relevant, mechanistic, exposure-driven. We don't know exactly how we are going to do it yet. We have just started." But it will begin by following the ICCVAM roadmap, he concluded.



Dr Emma Davies
Reporter

Related Articles

- Iccvam makes 'significant progress' on implementation plans for NAMs

- **Further Information:**
- ICCAVM Public Forum

Canada seeks voluntary feedback on two substances

30 May 2019 / Built environment, Canada, Data

The Canadian government is conducting voluntary information-gathering exercises for two substances: butanone oxime and ethylbenzene.

Information received on 2-butanone oxime – also known as butanone oxime or MEKO – will be used to evaluate a risk management measure associated with the substance's use in consumer alkyd paint and coating products applied indoors. Issued in 2014, the 'code of practice' sets out preventative measures intended to reduce inhalation exposure during these applications.

The questionnaire is applicable to anyone who manufactured, imported or sold interior or dual-use consumer alkyd paint and coating products containing the substance last year.

In a separate notice, the government has also notified a voluntary information collection on benzene, ethyl-, also known as ethylbenzene. This is intended to inform the potential development of significant new activity (Snac) provisions to monitor changes in exposure to the substance from consumer products like lacquers, stains, varnishes and concrete floor sealers.

The questionnaire applies to those who, last year, manufactured or imported interior or dual-use lacquers, stains, varnishes, concrete floor sealers or similar consumer products containing ethylbenzene, at a concentration equal to or above 1% by weight.

Responses to both inquiries will be accepted until 12 July.

Related Articles

- Canada issues code of practice for butanone oxime
- Canada releases final screening assessments

- **Further Information:**
- Butanone oxime
- Ethylbenzene

Building products standard introduces supplier ingredient reporting

30 May 2019 / Built environment, Data, North America

The Health Product Declaration (HPD) Collaborative has released an update to its standard for reporting the chemical content of building products and associated health information.

HPD Collaborative is a not-for-profit organisation with over 200 members representing the building industry, including architects, designers, building owners, manufacturers, consultants, tool developers and standards organisations.

The updated standard – HPD Open Standard Version 2.2 – introduces the Supplier HPD, a specification and methodology for enabling standard-based ingredient reporting and transparency throughout the building product supply chain.

Using the standard, manufacturers are able to "provide accurate, reliable and consistent information to decision makers – architects, designers, building owners – to enable the selection of products featuring transparency and healthier building materials".

The global supply chain is a complex and constantly evolving network, the Collaborative said. "One of the greatest challenges for a manufacturer who wants to participate in transparency reporting, using the HPD Open Standard, can be to determine the chemical contents of their own products."

Mike Manzi, associate principal at Bora Architects, an HPD member, said: "As we work to optimise product selection for healthier choices, we often need to make tradeoffs. The ability to understand more about how and where a substance appears in a product will be very helpful in our evaluation process."

William Paddock, managing director of WAP Sustainability, a consultant and HPD member, added: "We work closely with manufacturers and their suppliers on reporting supply chain information. Managing all the interactions and information flow about ingredients is definitely one of the most challenging aspects of transparency."

Further Information:

- HPD Standard update

REACH & CLP Hub: Echa/Efsa guidance on endocrine disruptors – challenges and experiences

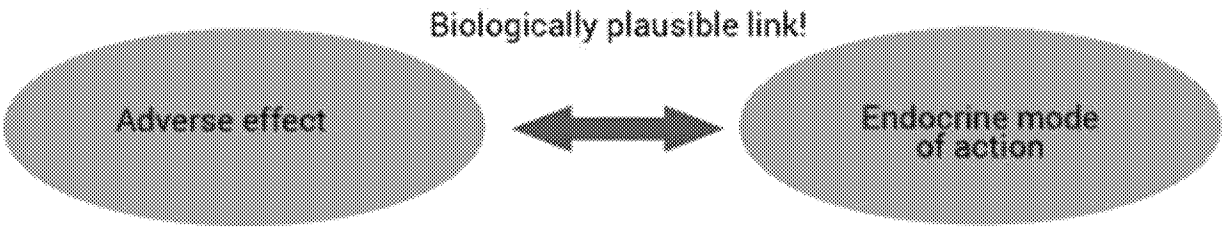
30 May 2019 / BPR, CLP Regulation, EDCs, Europe, REACH

Dr Martina Duft, ecotoxicology/regulatory affairs expert at knoell Germany GmbH, examines the best practice for implementing and dealing with the new ED criteria.

Endocrine disruptors (EDs), their definition and criteria, along with feasible options for testing and assessment have been extensively worked on and discussed in science and regulatory panels, in public and in the arena of national and global politics.

Since 2002, the WHO/International Programme on Chemical Safety definition of an endocrine disruptor has been unanimously agreed upon as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in an intact organism, or its progeny, or (sub)populations."

Consequently, distinct adverse effects and their causal relationship to substance exposure need to be established by a proven endocrine mode of action (see Fig 1 below).



Only as a result of tediously detailed and fierce discussions, were the scientific criteria for their identification in the field of plant protection products (PPPs) and biocides agreed according to the same definition. Thus, the WHO definition, which does not consider potency, is now the chosen regulatory approach in the EU.

Overall, for PPPs and biocides a 'hazard-based' approach (for the general public) is being applied, with its implications that substances can be banned without taking into account exposure or risk assessments.

Derogations for PPPs and biocides (professional uses) may be granted, but only if:

- negligible exposure (PPPs) or negligible risk (biocides) can be demonstrated; or
- the necessity of the substance to combat serious pests, which cannot be achieved by other available means, can be shown (PPPs and biocides); or
- there are disproportionate negative impacts on society by non-approval of the substance compared with the risks (biocides only).

The criteria have been applicable since April 2018 for biocides and since November 2018 for PPPs.

'Several pieces of legislation are relevant to endocrine disruption in the EU. In addition to the plant protection products Regulation (PPPR) and the biocidal products Regulation (BPR), REACH and the cosmetics Regulation are the main focus'

Several pieces of legislation are relevant to endocrine disruption in the EU. In addition to the plant protection products Regulation (PPPR) and the biocidal products Regulation (BPR), REACH and the cosmetics Regulation are the main focus.

Under REACH Article 57(f), endocrine disruptors are eligible as SVHCs with an equivalent level of concern as for PBT (persistent, bioaccumulative, toxic) or CMR (cancerogenic, mutagenic, toxic for reproduction) substances. Thus, generally they might be subject to authorisation, including socio-economic analysis.

The cosmetics Regulation is still under review (since 2015) and, with the criteria adopted for PPPs and biocides, new developments should be notified soon.

To enable authorities and applicants to properly implement and deal with the new criteria in practice, in June 2018, Echa and the European Food Safety Authority (Efsa) published a guidance document.

It must be noted that the new ED guidance is, to date, only applicable for PPPs and biocides (as are the ED criteria). However, it is a comprehensive guidance document prepared with Echa's involvement and because harmonisation across legislation is desirable, it is likely to be a reference when looking at ED properties under REACH and other regulations.

New ED guidance – overview and important elements

ED assessment, as specified by the guidance, is divided into five consecutive steps:

1. Mode-of-action analysis

During this first step, all available data are compiled, evaluated and summarised. This not only implies data or studies included in the respective dossiers, but also relevant and reliable results from a comprehensive literature search, in silico profiling and all other available data (for example, information from ToxCast, or any other database). The data are fed in every detail into Table Annex E, an excel template provided by Echa/Efsa, and a related data matrix is created.

2. Assess the evidence

Next, the obtained data and results are assembled, assessed, integrated and reported into lines of evidence both for adverse effects and endocrine activity, considering oestrogen, androgen, thyroid, steroidogenic (EATS) modalities.

3. Initial analysis of the evidence

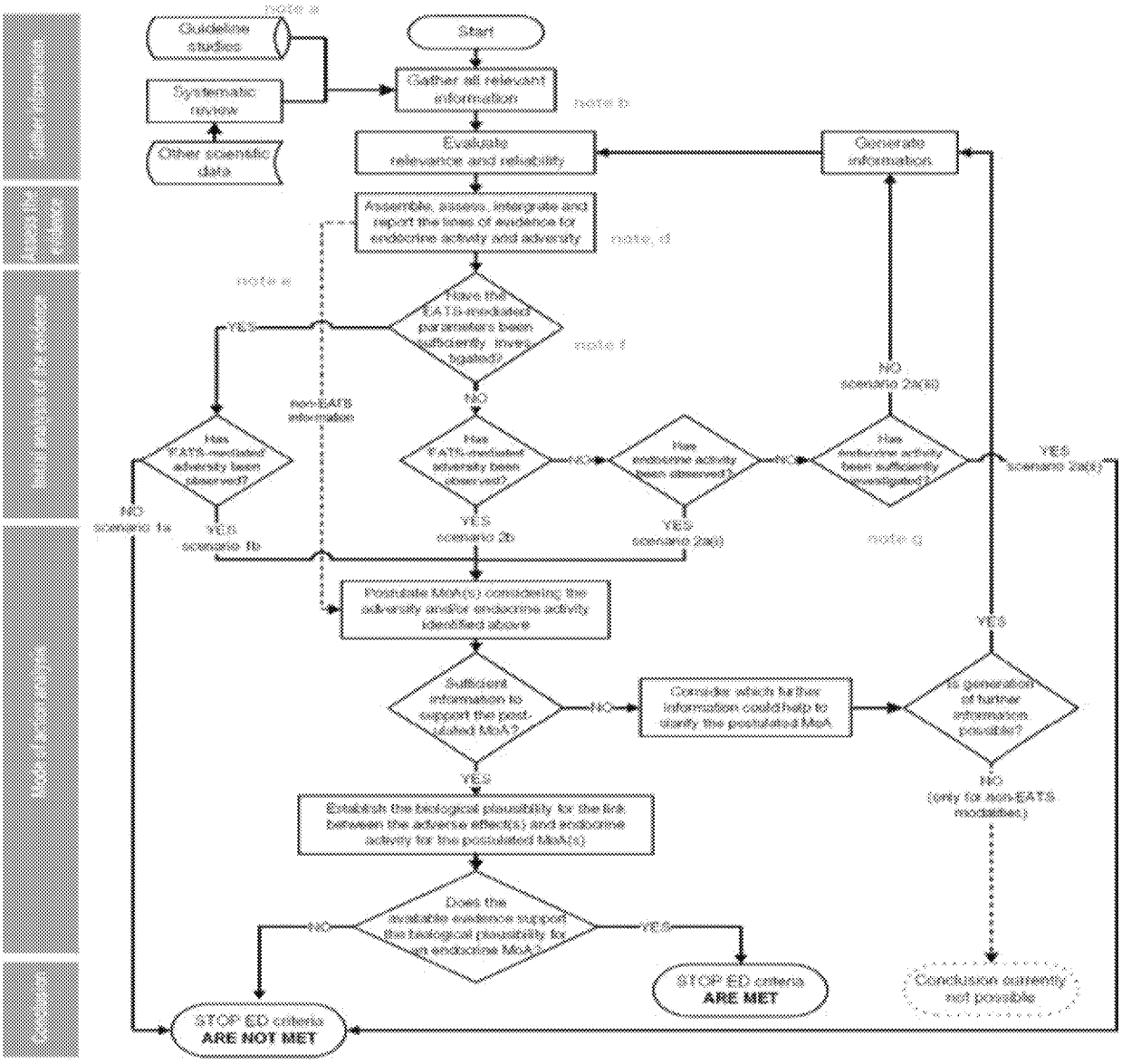
During this analysis, several questions need to be addressed: whether EATS-mediated parameters and/or endocrine activity have been sufficiently investigated and/or EATS-mediated adverse effects/endocrine activity have been observed. Depending on the outcome (see Fig 2 below), generation of new data or a mode-of-action analysis is triggered.

4. Mode-of-action analysis

If triggered, a mode-of-action analysis is requested: a mode of action should be postulated, considering all observed effects or data on endocrine activity. If there is sufficient evidence to support this hypothesis, the biological plausibility of this link should be substantially supported including relevant evidence.

5. Conclusion

Finally, a conclusion regarding the decision 'ED criteria met or not met' should be drawn based on the above mentioned steps and weight-of-evidence argumentation.



When involved in ED assessments, one quickly realises that, due to the focus of the guidance, an in-depth reevaluation of all available relevant (eco)tox studies is required in most cases.

In this context, the 'Table Annex E' is a central element and considered the basic tool for data gathering and subsequent assessment of potential ED properties.

It should be user friendly to facilitate the data gathering/evaluation process. Experience has shown that existing evaluations and summaries of good quality guideline studies can be transferred into this table only to a limited extent and a great deal of manual work is still required.

Besides this, the integration and assessment of the lines of evidence and potentially a subsequent substantial mode-of-action analysis (which depending on the effects observed may or may not be required) are core elements in the guidance and represent further big challenges in the assessment.

Impressions and first experiences

The words 'mammoth guidance' is the first impression of the document.

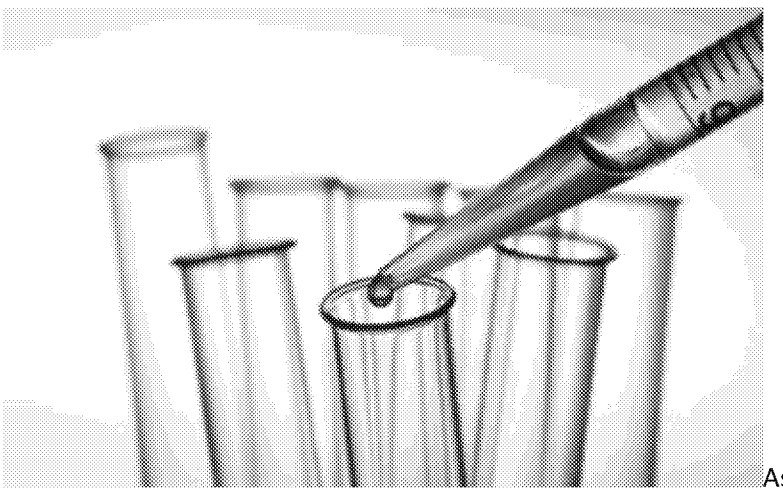
Without question, it is science-based and in-depth covering all facets for the assessment of potential endocrine disrupting properties with a focus on EATS-mediated endpoints. In fact, there is limited room for escape clauses or 'waivers'. And it is evident that the guidance is mainly applicable for data-rich substances; those with a complete data package consisting of studies complying with the most recent guidelines (OECD; the US Office of Prevention, Pesticides & Toxic Substance, etc) and investigating the required ED endpoints.

This is, to date, only the position for very few substances and concerns mostly active substances already suspected of possessing such properties.

All parties applying the guidance are still in the learning process. However, initial experiences show it to be very time-consuming, and presenting a substantial cost factor in active substance approval/renewal processes as well as PPP and biocidal product authorisations.

New testing requirements vs minimising animal testing – what is 'sufficiently investigated'?

There are justified concerns that the testing foreseen to investigate ED properties will conflict with the overall regulatory and ethical goals to minimise animal testing.



As stated in the guidance, in principle the ED assessment should be performed on the basis of all available data and testing shall not be foreseen in the first instance. This approach is in accordance with the principles of the BPR and PPPR where animal testing shall be the last resort.

However, the critical issue encountered is that even for data-rich substances with a complete (eco)tox data package (thus in complete accordance with the data requirements) consisting of high quality guideline studies, the relevant endpoints/targets and the information required for a proper and conclusive ED assessment have not "sufficiently been investigated" – not to mention for (biocidal) active substance for which the data package has been built on many waivers. From a strict scientific but also "tick the box" perspective, these data gaps would need to be filled and the generation of new data required.

Since the burden of proof on the absence or presence of ED potential is on the applicant, a pragmatic approach should be applied and the assessment conducted on the basis of information available, not least with regard for animal welfare.

Specifically for non-target organisms, a huge number of animals (fish and amphibians) would be needed to conduct the required comprehensive time- and cost-intensive studies for all substances. If animal studies are indicated of necessity, the testing strategy is to be developed, discussed and decided upon in close collaboration with the evaluating competent authority, possibly including Echa's ED expert group.

Recommendations for applicants and registrants

Assessment of ED properties (specifically according to the new ED guidance), as well as the generation of relevant data, is new territory for many applicants.

Without in-depth experience and training in (eco)toxicological evaluations in general, and in ED assessments in particular, expert advice and support is indispensable in order to avoid a 'got lost' situation.

> *'It is highly recommended that applicants and registrants have support from experts who have built up comprehensive knowledge in this area in order to avoid wasted time and resources.'*

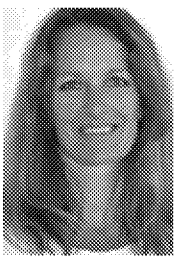
When dealing with such assessments for the first time, it is highly recommended that applicants and registrants have support from experts who have built up comprehensive knowledge in this area in order to avoid wasted time and resources.

Filling in Table Annex E and the integration of the lines of evidence are very time consuming and need to be meticulously conducted, requiring expertise in the fields of (eco)toxicology.

With respect to 'data generation', it is extremely important to discuss and align the testing strategy with the competent authority in case further data is required and in order to draw a definitive conclusion on the presence or absence of potential ED properties.

Based on the principles of the PPPR and BPR as well as ethical considerations, animal testing should not be the favoured option in the first instance.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch.



Dr Martina Duft
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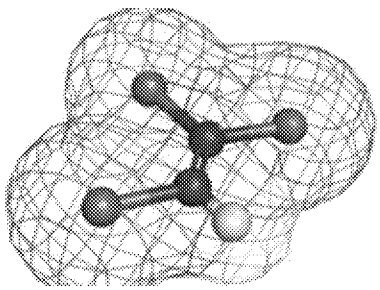
SVHC use fee could improve substitution under REACH, expert says

Measure may remove unhelpful incentive created by authorisation process, Setac hears

30 May 2019 / Alternatives assessment & substitution, Europe, Risk assessment



A fee for the use of all substances of very high concern (SVHCs) under REACH would, in some cases, remove an incentive to make substitutions that are not obviously of benefit, an economics expert has said.

Speaking at the annual conference of the Society of Environmental Toxicology and Chemistry (Setac) conference in Helsinki this week, Daniel Slunge, a researcher at the University of Gothenburg in Sweden, said that trichloroethylene (TCE) provided a useful example.

In general, companies were moving away from the use of TCE because it is on the authorisation list in Annex XIV, he said. The listing means that, if they want to use it, they have to first obtain authorisation for their specific use by applying to Echa.

However, some of the companies were substituting perchloroethylene, he added. This is significant because, while perc is not on the authorisation list, it is an SVHC on the candidate list.

He said that an SVHC use fee would remove the incentive to substitute TCE for perc, which is not an obviously beneficial substitute. More generally, it would also:

- provide continuous incentives for substitution;
- level the playing field for companies that are not using SVHCs; and
- stimulate innovation in alternatives.

SEA benefits reporting

Dr Slunge also recommended making the current fee for submitting an application for authorisation proportional to the benefits reported in the socio-economic analysis (SEA).

SEA is a key feature of the REACH process for obtaining authorisation. To gain this for a use, a company must first show that there are no alternatives and then that it is justified in socio-economic terms. Typically, the company does this through cost-benefit comparison.

Echa analysis published in 2017 found that applicants often overestimate the benefits of continued use, while underestimating the negative impacts on workers and the general public.

Dr Slunge said making the application fee proportional to the benefits of continued use reported in the SEA, would discourage this behaviour.

EU politics

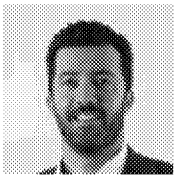
At the same event, Jessica Coria, also from the University of Gothenburg, provided preliminary project results, showing that the activity of individual EU member states in the authorisation process aligns with local interests.

The project team compared SVHC proposals – which are submitted by member states or Echa – to local production of the target substance. The results show that those submitted by a particular member state are generally for substances that are not produced there.

The team also looked at whether member states tended to submit supportive or non-supportive comments during the consultation on the proposal. They found that the UK was anomalous in this regard, submitting an unusually high proportion of non-supportive comments.

On 23 May, at the Helsinki Chemicals Forum, Matti Vainio, head of Echa's risk management implementation unit, said that the authorisation process had "few friends" but was a "major driver" of substitution.

He attributed poor perception to its newness compared with other regulatory risk management processes and to the relatively high degree of ambiguity in the legal text.



Andrew Turley
Science editor, Chemical Watch

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- 2017 Echa report on applications for authorisation

Dutch government prepares safe-by-design proposal for Horizon Europe

Work based on Safe Chemicals Innovation Agenda, Setac hears

30 May 2019 / Alternatives assessment & substitution, Netherlands, Risk assessment

The Dutch government is hoping to win EU funding for safe-by-design approaches to chemicals management from the incoming framework programme for scientific research, Horizon Europe.

A working group at the Ministry of Infrastructure and Water Management is working on a proposal based on its Safe Chemicals Innovation Agenda, published last year.

Speaking at the annual conference of the Society of Environmental Toxicology and Chemistry (Setac) in Helsinki on Tuesday, Jochem van der Waals, senior policy adviser at the ministry, said that industry and regulators needed to move away from "drop in" substitutions and towards more "fundamental solutions" to unsafe chemicals.

"Not just alternative chemicals, alternative materials, alternative processes, non-chemical solutions – even alternative business models," he said.

There are three streams to the proposal:

- improving methodologies;
- thematic R&D; and
- enabling the safe-by-design environment.

Regarding methodologies, Dr van der Waals said that stakeholders need more harmonised criteria for what is 'safe' and that ideally those criteria would be quantitative.

Toxicology tools for the design process and guidelines for product designers are also needed.

Challenges include:

- addressing the "value laden aspects" when determining safety;
- ensuring the accessibilty of data needed to assess alternatives; and
- involving supply chain actors, when considering the function of a chemical substance.

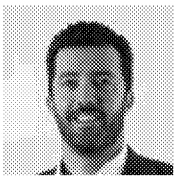
"It's important to involve actors in the supply chain before starting on the technical R&D," Dr van der Waals said. "Sometimes you don't need really fundamental R&D but maybe you do need a testing programme."

The proposal is expected to be finalised in June.

EU funding landscape

Horizon Europe, which will run from 2021-27, is the successor to the current EU framework programme for scientific research, Horizon 2020. This was was allocated €77bn for 2014-20.

In April, the European Parliament adopted a set of partial agreements that gave the go ahead, but the total budget remains under discussion.



Andrew Turley
Science editor, Chemical Watch

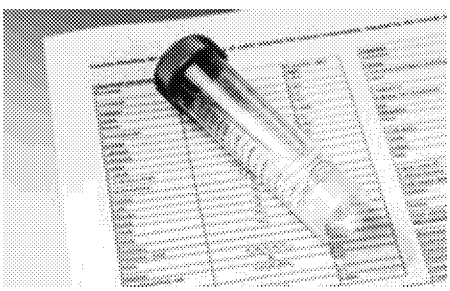
Further Information:

- Safe Chemicals Innovation Agenda

China seeks risk assessment data for 24 substances

Most substances are SVHCs in Europe

30 May 2019 / China, Data, Risk assessment, Voluntary action



China's Solid Waste and Chemicals Management Center (MEPSCC) has asked industry for data on 24 chemical substances.

According to a notice issued on 27 May, the MEPSCC – part of the Ministry of Ecology and Environment (MEE) – is conducting research on the listed chemicals. After receiving the relevant information, the ministry will begin its own risk assessments.

Most of the substances on the list are classified as substances of very high concern (SVHCs) in the EU and require authorisation before use, or are restricted under Annex XVII of REACH. Multiple jurisdictions around the world have identified them as requiring risk assessment.

The substances are:

- benzene;
- bisphenol A (BPA);
- pentadecafluorooctanoic acid (PFOA);
- 1-methyl-2-pyrrolidone (NMP);
- 4,4'-methylenedianiline /4,4'- diaminodiphenylmethane (MDA);
- 4,4'-methylenediphenyl diisocyanate;
- 4-methyl-m-phenylene diisocyanate *and* 2-methyl-m-phenylene diisocyanate (in Chinese, these substances have one name but refer to two substances, with two Cas numbers);
- dibutyl phthalate (DBP);
- benzyl butyl phthalate (BBP);
- bis(2-ethylhexyl) phthalate (DEHP);
- diisobutyl phthalate (DIBP);
- 4,4'-methylenebis[2-chloroaniline];
- toluene;
- 1,2-dichloropropane;
- pentachlorobenzenethiol;
- tris(2-chloroethyl) phosphate;
- phenol, isopropylated, phosphate (3:1);
- octamethylcyclotetrasiloxane (D4);
- 2,4,6-tri-tert-butylphenol;
- 1,2-dichloroethane (EDC);
- 1,4-dichlorobenzene;
- chloromethyl methyl ether; and
- N,N-dimethylformamide.

Information sought includes:

- physico-chemical properties;
- toxicological data;
- production and use quantity;
- use and production methods; and
- environmental exposure data.

The MEPSCC is encouraging enterprises and individuals across all sectors to contribute data. This can be submitted via email or post until 31 August.

Existing chemical regulation

In China, there is currently no mandatory system for submitting data on existing chemicals. But, in January, the MEE introduced the draft Regulation on the Evaluation and Control of Chemical Substances, which will overhaul the management of both new and existing chemical substances in the country.

The new regulation aims to implement a requirement for annual reporting. This must include the names of substances, uses and quantity produced, used or imported in the previous calendar year with no small volume exemption, which is expected to create a heavy burden for industry.

Under the proposals, the MEE will organise environmental risk screening and prepare and publish an inventory of substances subject to priority evaluation. Companies producing, using or importing the substances will have to provide the above mentioned data.

Ellen Tatham
Asia reporter

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- China consults on chemical framework overhaul
- **Further Information:**
- MEPSCC notice (in Chinese)

EU consults on metal limits in ceramic, glass table and kitchenware

30 May 2019 / Europe, Food & drink, Food contact Regulation 10/2011, Metals

The European Commission has requested feedback on a proposal to lower heavy metal limits in ceramic, glass and enameled table and kitchenware.

Current lead levels vary from 0.8mg/dm2 to 1.5mg/l and 4mg/l, depending on the article, and cadmium levels vary from 0.07mg/dm2 to 0.1mg/l and 0.3mg/l, depending on the article.

New scientific evidence has indicated that current limits on lead and cadmium in these food contact materials (FCMs) should be revised so as to provide adequate health protection.

The EU is also considering setting new limits for other metals. It aims to align EU law on glass and enameled metals.

The feedback period runs from 29 May to 26 June.

In October last year the Commission officially started the evaluation process for the EU's food contact materials legislation.

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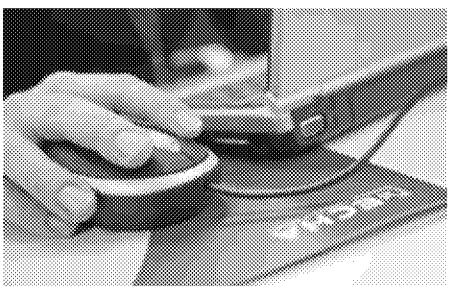
REACH registration phase 'not over' – Cefic

One year on, dozens of dossiers pending; new submissions being made

30 May 2019 / Europe, REACH, Substance registration



A year has passed since the final REACH registration deadline, but it would be "misleading to think that the registration phase is over", Cefic has said.

Companies submitted their dossiers on 31 May last year and by the next day a total of 88,319 registrations had been logged for 21,551 substances over the three tonnage-band deadlines.

The REACH Directors' Contact Group (DCG) – an informal group of directors from the European Commission, Echa and industry associations – did, however, approve 576 requests under "exceptional circumstances" for an extension to submit the data.

Now, almost all of these have successfully completed their registrations with 25 remaining. These have a deadline of 1 June, Echa told Chemical Watch.

The agency has processed a further 6,968 registrations for 785 substances that came in after last year's deadline. However, Echa said it should be noted that these registrations are not all late submissions: "They could also be new market entrants who have to register before placing their chemical on the market."

And in a statement to Chemical Watch, Cefic emphasised this point, saying that the market is dynamic and that "almost every day we see new substances, uses and applications, as well as new players appear[ing] on the market".

Reflecting on the REACH milestone, the industry association said the most impressive achievement is that "we have managed to create the most comprehensive database on chemicals, their properties, uses and behaviour in the world".

Meanwhile, Echa said it recognised early on that REACH registration could be burdensome for SMEs – mainly because of the cost of data. "We did our best in helping SMEs with simpler IT tools, DCG recommendations and solutions. The availability of laboratories to perform the tests was also quite challenging, but we were able to address this issue with the DCG solutions." Reaching out to the smaller non-organised companies was "hard", it added.

'Disappearing' substances

As the final registration date neared, some in industry feared certain chemicals would drop off the market because companies would not be able to register them.

Speaking to Chemical Watch this week, Cefic said that as far as it is aware, "the absolute majority of the substances used on the market has been successfully registered allowing the chemical industry to continue supplying its markets and customers with no disruptions".

Echa, meanwhile, said it has "not heard" of substances disappearing from the market. The agency had discussions with industry ahead of the deadline on the potential disappearance of substances – but no potential disruptions were identified.

Monitoring the situation in collaboration with industry associations will be an ongoing exercise. "We also continue to encourage the customers using chemicals to still be active and clarify whether crucial substances for their businesses are registered."

The agency pointed out that figures communicated prior to the deadline were "forecasts or estimates" done more than 10 years earlier and not actual expectations.

European trade body SMEUnited, formerly known as Ueapme, was instrumental in airing concerns over potential missing substances. Today, in specific markets there is some evidence of a shortfall, advisor Marko Susnik said.

"It seems that we have a massive bottleneck in the field of some pigments, which are especially used in the textile industry." There are several factors contributing to this, he added, but REACH is an important one.

"In other areas we already observed a couple of cases where mixtures needed to be reformulated because suppliers decided to exclude substances from their portfolio."

Speaking more broadly, "we cannot observe a more general trend of disappearing substances. But it is too early to say, there should be still stocks available from before the last deadline. Those can be still sold to fill supply gaps."

Registration effort

The investment made by registrants should not be "underestimated", Cefic said. According to its calculations, the time and effort that goes into an average registration dossier consists of:

- completing more than 2,000 data fields in Iuclid;
- up to 70 physico-chemical, toxicological and ecotoxicological studies;

- 100-150 hours of work;
- studies that can take one to two years to complete;
- additional time and resources spent negotiating with consortia;
- complex use and exposure assessment; and
- the need to maintain and update dossiers.

Echa and industry are now ramping up work on evaluation under REACH. Last week the agency announced it is quadrupling the number of compliance checks it carries out to a fifth of all REACH registration dossiers in a fresh attempt at tackling non-compliant information on chemicals.

Luke Buxton
Europe editor

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- Industry concerned about 'missing' REACH 2018 substances
- Echa to quadruple number of compliance checks on REACH dossiers
- Cefic, regulators promise action on REACH dossier non-compliance

- **Further Information:**

- Echa registration infographic

Switch to chromium III from VI despite Corap evaluation, Echa suggests

Assessment of reprotoxic properties should not be a deterrent

30 May 2019 / Aerospace, automotive & engineering, Alternatives assessment & substitution, Europe, REACH, SVHCs

Companies looking for safer alternatives to the SVHC chromium (VI) trioxide could switch to chromium (III) oxide, even though it is under evaluation for its potential hazardous properties, a senior Echa official has said.

Speaking at the agency's substitution and innovation network meeting in Helsinki on 29 May, Matti Vainio, head of risk management, said the fact chromium III is on the community rolling action plan (Corap) "does not mean that you don't look at it".

He was responding to comments from Eurometaux REACH advisor Hugo Waeterschoot that industry is reluctant to invest in chromium III as a substitute for chromium VI "if it will be another hurdle".

Chromium VI has carcinogenic and mutagenic properties and has been subject to authorisation since 2017. Its use in electronic equipment is already banned in the EU via the RoHS Directive.

The substance is widely used in industry with key applications including:

- chromate pigments in dyes, paints, inks and plastics;
- chromate anticorrosive agents in paints, primers and other surface coatings; and
- chromic acid electroplated onto metal parts to provide a decorative or protective coating.

Meanwhile, this year, France is evaluating chromium III as a suspected reprotoxin and sensitiser. A justification document published in March shows it may be considered for harmonised classification under CLP, but not for restriction or authorisation.

Mr Vainio told the meeting that companies should not stop substituting to chromium III as it is not a carcinogen. "It has maybe reprotoxic [properties] but I wouldn't hesitate to go to chromium III," he said.

Synergies

The slow pace of substituting SVHCs has been a key concern under REACH. Echa has outlined activities to promote substitution and it is currently updating its strategy for 2020-2021, but lack of reliable data on alternatives and the high cost and technical difficulties of switching remain key barriers.

Many companies are reluctant to even consider alternatives due to a "fear of change", said Audrone Alijosiute from the Baltic Environmental Forum Lithuania.

Some users of chromium VI are not aware of the necessity to find a substitute "because it works so well", said Dr Michaela Clever from Germany's Federal Institute for Occupational Safety and Health (Baua).

The meeting in Helsinki, the second organised by Echa on substitution, emphasised the need to create information networks between stakeholders to encourage substitution and accelerate the take-up of alternatives.

There should also be more synergies between different industries to maximise available information on alternatives, which could then benefit all, conference participants heard.

Mr Vainio said companies should share information on alternative substances, even with those in other sectors, as similar substances and challenges might also impact them.

Paavo Heiskanen, REACH officer at the European Space Agency (ESA), talked about the importance of "adversarial collaboration" where competing industries may centralise resources to test alternatives and share information. It would

be beneficial for ESA, for example, to collaborate with the European Defence Agency (EDA) on substances like chromium VI, he said.

The substance is used in aerospace applications due to its corrosion-limiting properties. Echa has approved plating treatments for aerospace use through 2024 and some chromium VI additives for aerospace paints through 2026.

Other initiatives

Regarding data on alternatives, Echa has cancelled its own plans to publish a 'user-friendly' shortlist compiled from authorisation applications, citing a lack of resources. However, there are other initiatives among member state competent authorities and NGOs.

Germany's Baua, for example, is updating its information portal for substitution, Subsport, for relaunch in 2020.

Developed in 2010, Subsport has provided free information on chemical alternatives as well as guidance for substance evaluations and substitution management. The project was revived in 2018 and a new website, Subsportplus.eu, is under construction, Dr Clever said.

Clelia Oziel
Europe correspondent

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- Resource issue kills Echa 'user-friendly' alternatives data plan
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- Corap on chromium III
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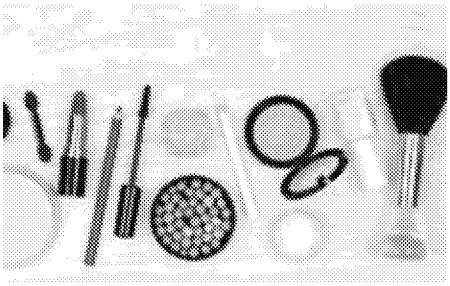
Cosmetics fragrance disclosure bill clears California Senate

Right-to-know bills also looks to tackle allergens

30 May 2019 / Confidentiality & right-to-know, Personal care, US states



California's Senate has approved a bill to require increased disclosure of fragrances or flavours of concern in cosmetic products.

Now under consideration in the state's Assembly, the Fragrance and Flavor Ingredient Right to Know Act of 2019 (SB 574) calls forexpanding existing cosmetics disclosure requirements to fragrances or flavours that appear on any of more than 20 designated authoritative lists.

The set of lists aligns with those included in California's cleaning products ingredient disclosure law, and includes substances:

- listed as reproductive toxicants or carcinogens under California's Proposition 65;
- on the EU's candidate list of substances of very high concern (SVHCs);
- identified by the International Agency for Research on Cancer (Iarc) as group 1, 2A or 2B carcinogens;
- named as neurotoxins by the Agency for Toxic Substances and Disease Registry (ATSDR); and
- reproductive or developmental toxicants identified by the National Toxicology Program (NTP).

Companies would need to disclose the presence of any of these substances in cosmetics, and whether the product is intended for consumer or professional use.

It also would require companies to notify fragrance allergens, as included in Annex III of the EU's cosmetics Regulation, present in a rinse-off cosmetic at a concentration above 100 parts per million or in a leave-on product above 10ppm.

If adopted into law, reporting to a division of the state's Department of Public Health on such products would be mandated from 1 July 2020. The state, in turn, would be directed to make the information available in a database, along with information on the health hazards associated with each ingredient.

A provision in the legislation addressing trade secrets specifies that manufacturers would not be required to disclose the weight or amount of an ingredient used, nor formulation details. And a company is permitted to maintain as trade secret any ingredient or combination of ingredients that are not allergens or that do not appear on a designated list.

'Hidden' ingredients

Breast Cancer Prevention Partners, one of the bill's sponsors, says that existing federal laws allow "dozens – sometimes even hundreds – of chemicals to hide under the word 'fragrance' on the product labels of beauty and personal care products."

This, the NGO said in testimony this spring, leads the public to being "exposed to a shocking number of unlabelled, unregulated toxic fragrance and flavour chemicals ... without their knowledge or consent." The legislation would address this issue, it said.

But several industry groups, including the Personal Care Products Council and the California Chamber of Commerce, told the legislature that the bill was duplicative of existing state and federal law and "unfairly punishes an industry that has led the way on all intentionally-added ingredient disclosures."

Cosmetics have listed ingredients in order of predominance since the 1960s, said the industry groups. And "the belief that fine fragrances present a human health hazard is unfounded," they added.

The bill passed the Senate on 29 May by a 23-10 vote.

Kelly Franklin
North America editor

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- California legislature continues to advance chemical bills
- California, Rhode Island consider expanding cosmetics ingredient disclosure
- California cleaning disclosure bill unites NGOs and industry

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- SB 574

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